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Achieving Operational Excellence: An In-Depth Case Study with Nubinno and Siegfried

As a leading global contract manufacturer, Siegfried seeks to provide excellent service and operational performance for its life sciences customers. This session covers:

- How Siegfried organizes its manufacturing operations.
- The relationships Siegfried maintains with customers and the key performance indicators (KPIs) underpinning relationships.
- The investments Siegfried has made to achieve operational excellence.

Speakers also cover the role that supply chain digitalization and network orchestration can play in further enhancing Siegfried’s operational leadership.

Featured Speakers:

Mark Dalli
Head of Operational Technology DP
Siegfried

Jaroslaw Radzikowski

CEO and Head of Delivery

Nubinno

TRANSCRIPT

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Dan Walles: Well, gentlemen, thank you for joining us today. Maybe we can get things started a bit here with some introductions of yourself, maybe your role in the organization and a little about your company as well. Mark, do you want to join?

Mark Dalli: My name is Mark. I'm from Malta, a very small island in the middle of the Mediterranean Sea. I work at Siegfried, which is a global leader in the CDMO industry, and I'm the head of operation and technology for our drug products.

Jaroslaw Radzikowski: My turn. Hi. My name is Jaroslaw Radzikowski. That's the really long name that hardly anyone can pronounce. I'm the CEO and head of delivery of Nubinno. As Dan mentioned, we've been a service partner for TraceLink for a long time now. We are a company based out of Warsaw, Poland, with teams based in several countries in Europe as well as in India, China, and Japan.

What we do, we do consulting for our customers on the supply chain. Of course, it all started with serialization, and track and trace. Now what we do for our customers, we help them to ensure that when they get into new markets, when they expand their supply chains, when they get new products, we're there for them.

We also do transitional projects when companies acquire companies or parts of the companies. We help with this fragile moment to move from one to another in a seamless way. There's also other things, follow us on LinkedIn to learn more. [laughter]

Dan: Great. Thank you, gentlemen. Mark, why don't we start with Siegfried. We know about some of the regulations, but talk about ultimately how you started with serialization, and maybe some of the learnings about that.

Mark: Ultimately, Siegfried is a global CDMO. We have 13 locations globally, and that meant that several of our locations within our drug products systems needed to comply to the market regulations, to the new upcoming EU FMD, aggregation in the US, or crypto in Russia, for example. That meant that we needed to understand what was the impact.

The impact was throughout the whole company. We had impact in our supply chain in how we communicate with our customers, what information do we need, how it impacts the packaging lines, how it impacts our connection with the customer. There, we learned that we needed to create a strategy of how we are going to go forward with implementing this new solution.

There, we created partnerships, one of them being TraceLink, where we understood that we could harmonize our communication with our customers by creating B2B connections, and also optimizing that connection by having one partner being available for us and creating that connection.

Dan: We have a fairly compelling business regulatory driver for serialization that's going to really change the way you operate as a company. Jaros, maybe you can talk a bit about how you were working with Siegfried, and maybe what were some of the learnings about moving the organization into the operationalizing of serialization and compliance.

Jaroslaw: Sure. I think working with Siegfried but also other customers in Europe, we're having these three distinctive phases. Phase one was when the EU FMD Directive, the regulations were first introduced. That was until February 2019 and a couple of months after that for the grace period in few countries in Europe.

This was the moment where companies realized, we need to do this serialization thing, otherwise our stock is not sellable. There were different approaches. Some of the companies were just trying to find any type of solution just to get it done, and that's it, they can serialize, they can manufacture and package.

Some of the companies were a little bit smarter than that, and they looked at the global compliance solutions such as TraceLink because they looked at the thing holistically. They really planned ahead thinking about other markets, etc. There were different groups and approaches towards the introduction of serialization, at least in Europe, that we observed here.

Then after serialization was enforced, after the grace periods, companies realized serialization is not going away, it's staying with us, and not only that, all the regulations will be changing. European companies who actually sell in the US, they had to think about the regulations that are related to USD CSA type of requirements.

In Europe, we also have some changes that are happening especially on the country levels. There was also the whole drama with Brazil, and then we had also the crypto codes being introduced for Russia CIS countries that are happening now for Uzbekistan, Kazakhstan, and other countries.

This was the second phase where we really started understanding what we're doing, and companies started looking into optimizing their serialization activities. That was an extra strain on CMOs and CDMOs because, of course, MIHs would come with the ready requirements and needs they would have that even big CMOs would need to think about how to accommodate.

This was the period when they started looking, did we actually make the right decision in terms of our solution? Did we actually set up the team correctly? Do we have enough resources? Do we train our resources? What about our work instructions, and so on and so forth? That was the optimization period.

Also, if you think about it from the financial department perspective in all these companies, they wanted to look at the TCOs, so the total cost of ownership for the solutions they introduced. In most cases, that was for three to five years. Five years are actually exactly passing now in Europe beginning of this year.

Now, we are in phase three. The companies, they chose, they accommodated, they optimized, they may be changed in the meantime, and now we are in the phase three. The companies are actually looking for the benefits, we spent all this money, all this time, all this effort in introducing serialization.

We, as in Siegfried, we put all this effort into implementing TraceLink for all our markets, for all our customers, for the onboardings, for all this, what's next? What do we know next? What is the next thing that we can improve?

I think that's the biggest thing that we're looking at in this phase three, is to look at the full supply chain. How do we digitize the whole thing, not just serialization, and track and trace activities? This is where we are now, in my opinion.

Dan: Mark, maybe you can comment a little bit on, you talked about harmonizing the approach. What areas do you see that digitalization and serialization can help with in in other parts of your business?

Mark: Ultimately, it is a journey because you are creating digitalization according to your business requirements. You have to understand what your business needs are, and then you create targets towards them. From a digitalization perspective, some use cases that we did within Siegfried is that we automated a lot of the communications that we have between the different systems.

We automated our connection with our ERP to our level two, level ones, level three systems. We are looking into further automating other systems in order to reduce complexity, create leaner processes. In the end, we need to be more agile. We need to be able to provide on time and full to our customers with the highest quality possible.

That means that we have to automate processes to reduce human errors, and at the same time, we have to automate processes to improve and to make us more efficient.

Dan: This is to both of you. Where did you start? What processes did you start with as you started this operational process?

Jaroslaw: You want to take it?

[laughter]

Mark: The main idea is to create governance. Governance and harmonization, but you have to create a balance between standardizing, putting a line between local and corporate responsibility, and making sure that everyone knows what their responsibilities are.

At the same time, you need to make sure that the responsibilities that you put at corporate and local levels are set in a way that you're still agile enough to produce in an efficient manner. You don't to, for the sake of harmonization and governance, put everything at corporate level, and then impacting at the local teams.

Dan: That's a great point and something that we hear a lot, and you must see this a lot with Nubinno with some of the organizations that you work with. How do you help to achieve that balance?

There's benefits in standardizing an approach across all of your sites, maybe in all of your local markets, but there may be some good reasons why things are done in a different way in each of those markets. How do you go through that discovery? Hen how do you go through that assessment of what do we try to standardize and what remains unique or custom?

Jaroslaw: Yeah. That's a very good question. A few years back, I think it was two, three years ago, we started working with Mark on the idea of doing exactly what you mentioned. We came up with this project that we called VSE, a virtual serialization expert project that was exactly what Mark was saying.

Certain activities needed to be taken out from the local teams to create the global governance and one single point of contact for internal and external stakeholders. We did simple things like introducing of the ticketing system. We made sure that we described the roles for the global team members, how we triage, because as you said, there are differences.

If we're talking about the Siegfried site that is in the US, they produce for a different market than, for example, some sites in Europe. They would be maybe producing also different types of products, packaging differently, etc. What we did, we took a look at what type of customers are supported at each site. We did nice role descriptions, and we built it into the local vessels global.

At the moment, the customers of Siegfried internal and external, they can contact only one email address, one phone number, and they get all the support because we triage it and we help to resolve issues. That's the tactical side of things.

Strategically, we also review every now and then, periodically, what we've done, how we've done it, how long it took us. Going back to your question, we need to decide whether we did it right or maybe we need to change because it's not stable. We don't set things up forever. Everything is changing.

We go back and strategically look at it in order to make sure that we adjust and improve. That's why we are actually at the stage three, and we're here looking at broadly what to do next with the supply chain.

Dan: That's a great segue. Maybe start with Mark, what is next? You're continuing to iterate on the serialization projects. What are some of the other initiatives, maybe related initiatives, that Siegfried is kicking off?

Mark: Siegfried is always looking at continuous improvement, and that means that you have to find ways and means on how to improve yourself. That could mean simple stuff from creating SLAs to make sure that you are adhering to what you are promising to your customer. At the same time, you have to also find ways how to automate and digitize.

We are looking at how to further digitize our supply chain, how to further digitize our manufacturing with MES systems and whatsoever. There are several different steps that are being taken because ultimately, we need to improve.

Jaroslaw: If I can just add a quick note here.

Dan: Sure, please.

Jaroslaw: From the operational point of view, when we talk Siegfried works with customer A, it's not a one-to-one work. Within the company, we've got multiple departments. Within these departments, we've got multiple people working.

Then when we talk about the inventory management, procurement, customer support, artworks, master data management, whatever, you name it, we're talking about multiple people working in multiple departments to achieve one goal. Understanding exactly what is happening with all these different bits and pieces is what you need to do first in order to move on.

You need to capture a baseline of what you have now so we can move on. What we're doing now, which was Mark's initiative, where we started, because we believe that serialization-wise, Siegfried is really there, now, in order to look outside, we need to understand where is the supply chain team at? Where is the procurement at? Where is the customer support at?

What type of challenges and issues they face in order to come up with the next the next steps, next plans. That's the reason why we're here also.

Dan: Maybe a nontechnical question, and maybe talk a bit about the actual users, the folks that are operating on the line, or maybe they're managing the exceptions, help us understand how you got their buy-in to change. There's one way of just saying, you must change, that can have a negative effect. How did you help get their buy-in on what was coming and how to change their processes?

Jaroslaw: Is it a question for me?

Dan: Sure.

Jaroslaw: First thing Mark said to them, you must change.

[laughter]

Jaroslaw: Easy, and then we take it from there. Of course, it's a natural human thing to be averse of change, to be scared of change a little bit. At least the first reaction is, what's going to happen next? This is exactly what we need to address, and this is exactly what we've done. With the VSE project, because we're not getting into numbers and everything else, but it was a huge effort.

What we've done before we actually rolled it out, before we implemented it, we went through every single task that is being performed at each site. Siegfried also acquired in the meantime new sites from another company that was actually an MIH using SAP, ATTP, so there would need to be a switch to TraceLink. Then you're talking about 18 lines with four different systems to be changed, etc.

How do you convince people that the changes they're going through already are just the start? I think the data is very helpful, the analysis, the interviews, the discussions with...you cannot ignore anyone, everyone is important in the team. We appreciate this fact, and Siegfried, Mark, and Nubinno team supporting these activities. We did a lot of interviews.

We did a lot of mapping just to understand who can be the local and who can be the global support for all these activities. Then we basically involved all of them in these activities, in these discussions. We said, look, do we want to do it? They were actually saying, yes, no. They were part of this whole implementation.

Dan: Fantastic. Why don't we maybe start to wrap up a little bit. Let's start with Mark here. You've obviously had a lot of success in your project. What would be the one or two points of advice that you' give to the audience, to maybe some folks that are starting out or are looking at making some sort of a change?

Mark: You can get Nubinno to help you.

[laughter]

Jaroslaw: You can.

Mark: Ultimately, it revolves under three main aspects, is the way I see it. It's understanding what you are getting into, what are the requirements. Understanding what does the user need, because once you have the buy in of the user at whatever level it is, it will make your life much easier.

You need to plan for resources. You need to plan to have the resources at the right time and for the right period. If you do not plan to have the resources support you at the right time, then it will make a complete mess out of the project.

Dan: Maybe what advice would you give to folks in the audience?

Jaroslaw: There's nothing that teaches us more than mistakes we made. If you made these mistakes in phase one when you were choosing your serialization solution, try to analyze that and not make mistake now in phase three when you're thinking about digitizing your supply chain.

What I think is that digitizing supply chain is a buzzword at the moment. People talk about it, they define it differently. What is it really? That's a big question. If you think about it, this is the question you should be asking your team members.

Go to the supply chain, go to procurement, ask them, what challenges do you face? What is not that great at your work?

Compile all these questions, maybe even create a workshop with the guys who are handling serialization. They will help you to understand the biggest benefit that they already created for you, which is your network.

Based on these challenges and the fact that you already built network and you've got tracing system to use it that has this great platform, that is network-based platform, it becomes easier at least to discuss it, to get to the proof of concept, to test it, to play with the ideas because that's where it all starts.

Dan: Gentlemen, congratulations on your success. Certainly, a lot of hard work was done, lots to do going forward as well. Best of luck on that. Thank you for joining us today, really appreciate it.

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